

JFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Patrick Miles et al.

Title: Surgical Access System and Related Methods

Docket No.: 80100.023US1

Filed: June 26, 2003

Examiner: Unknown

Serial No.: 10/608,362

Due Date: N/A

Group Art Unit: 2831

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

☒ A return postcard.☒ An Information Disclosure Statement (2 pgs.), Form 1449 (5 pgs.), and copies of 24 cited documents.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 50-2040.

CUSTOMER NUMBER 30,328, (858-527-1936)

By: 

Atty: Jonathan Spangler

Reg. No. 40,182

7-27-04

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27 day of July, 2004.

MEREDITH MESCHER

Name

Meredith Mescher

Signature

(GENERAL)

S/N 10/608,362PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Patrick Miles et al.	Examiner:	Unknown
Serial No.:	10/608,362	Group Art Unit:	2831
Filed:	June 26, 2003	Docket:	80100.023US1
Title:	Surgical Access System and Related Methods		

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. § 1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 50-2040 in order to have this Information Disclosure Statement considered.

Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2) and has included for the examiner's consideration copies of International Search Reports for the following PCT applications: PCT/US00/32329, PCT/US01/18606, PCT/US01/18579, PCT/US02/22247, PCT/US03/02056, PCT/US/02/35047, and PCT/US02/30617 which are also list on the 1449 form enclosed herewith.

INFORMATION DISCLOSURE STATEMENT

Serial No: 10/608,362

Filing Date: June 26, 2003

Title: Surgical Access System and Related Methods

Page 2

Dkt: 80100.023US1

Applicant believes that the U.S. Patent & Trademark Office has waived the requirement under 37 C.F.R. 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication. The waiver is provided in a pre-OG notice from the U.S. Patent & Trademark Office entitled "Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003" and dated July 11, 2003. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

PATRICK MILES ET AL.

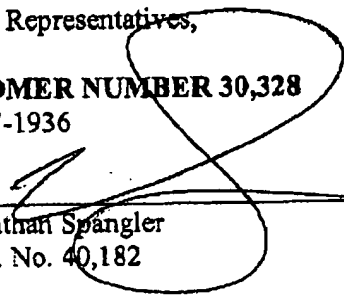
By their Representatives,

CUSTOMER NUMBER 30,328

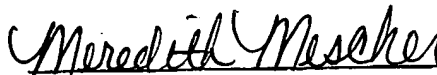
858-527-1936

Date 7-27-04

By


Jonathan Spangler
Reg. No. 40,182

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27 day of July, 2004.

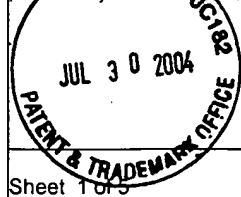
MEREDITH MESCHER
Name
Signature

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Sheet 1 of 5

Complete if Known

Application Number	10/608,362
Filing Date	June 26, 2003
First Named Inventor	Miles, Patrick
Group Art Unit	2831
Examiner Name	Unknown

Attorney Docket No: 80100.023US1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-2002/0007129	01/17/2002	Marino, J. F.	600	546	06/08/2001
	US-2002/0072686	06/13/2002	Hoey, M., et al.	600	547	05/18/2001
	US-2,704,064	03/15/1955	Fizzell, J. A., et al.	128	2.1	09/10/1952
	US-3,364,929	01/23/1968	Ide, W. S., et al.	128	172.1	12/21/1964
	US-3,664,329	05/23/1972	Naylor, R. N.	128	2.1 R	03/09/1970
	US-3,682,162	08/08/1972	Colyer, J. E.	128	2.1 R	12/04/1969
	US-3,785,368	01/15/1974	McCarthy, T. M., et al.	128	2.1 Z	08/23/1971
	US-3,830,226	08/20/1974	Staub, D. E., et al.	128	2.1 R	06/15/1973
	US-3,957,036	05/18/1976	Normann, N. A.	128	2.1 R	02/03/1975
	US-4,099,519	07/11/1978	Warren, F. E.	128	2.1 R	01/14/1977
	US-4,207,897	06/17/1980	Lloyd, J. W., et al.	128	303.1	07/13/1977
	US-4,224,949	09/30/1980	Scott, Norman R., et al.	128	734	11/17/1977
	US-4,235,242	11/25/1980	Howson, David C., et al.	128	695	04/02/1979
	US-4,285,347	08/25/1981	Hess, S. R.	128	785	07/25/1979
	US-4,291,705	09/29/1981	Severinghaus, John W., et al.	600	546	09/10/1979
	US-4,515,168	05/07/1985	Chester, M. H., et al.	128	741	07/22/1983
	US-4,519,403	05/28/1985	Dickhudt, E. A.	128	785	04/29/1983
	US-4,545,374	10/08/1985	Jacobson, R. E.			09/03/1982
	US-4,561,445	12/31/1985	Berke, Joseph, et al.	128	642	05/25/1983
	US-4,592,369	06/03/1986	Davis, Graham R., et al.	128	733	07/08/1983
	US-4,595,018	06/17/1986	Rantala, B.	128	733	06/06/1984
	US-4,633,889	01/06/1987	Talalla, A.	128	784	12/12/1984
	US-4,658,835	04/21/1987	Pohndorf, P. J.	128	785	07/25/1985
	US-4,744,371	05/17/1988	Harris, D. L.	607	117	04/27/1987
	US-4,759,377	07/26/1988	Dykstra, Dennis D.	128	733	11/26/1986
	US-4,807,642	02/28/1989	Brown, David A.	128	733	04/10/1987
	US-4,892,105	01/09/1990	Prass, R. L.	128	741	01/11/1988
	US-4,926,865	05/22/1990	Oman, P. S.	128	421	01/17/1989
	US-4,962,766	10/16/1990	Herzon, G. D.	128	741	07/19/1989
	US-4,964,411	10/23/1990	Johnson, Michael T., et al.	128	733	07/13/1989
	US-5,007,902	04/16/1991	Witt, H.	604	117	02/22/1989
	US-5,058,602	10/22/1991	Brody, Stanley R.	128	733	10/04/1989

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached



Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/608,362
Filing Date	June 26, 2003
First Named Inventor	Miles, Patrick
Group Art Unit	2831
Examiner Name	Unknown

Sheet 2 of 5

Attorney Docket No: 80100.023US1

	US-5,081,990	01/21/1992	Deletis, Vedran	128	642	05/11/1990
	US-5,092,344	03/03/1992	Lee, T.	128	741	11/19/1990
	US-5,127,403	07/07/1992	Brownlee, Robert R.	128	419 P	08/21/1990
	US-5,161,533	11/10/1992	Prass, Richard L., et al.	128	639	09/19/1991
	US-5,196,015	03/23/1993	Neubardt, Seth L.	606	61	04/30/1992
	US-5,255,691	10/26/1993	Otten, L. M.	607	117	11/13/1991
	US-5,282,468	02/01/1994	Klepinski, R. J.	128	642	01/08/1992
	US-5,284,153	02/08/1994	Raymond, S. A., et al.	128	741	04/14/1992
	US-5,284,154	02/08/1994	Raymond, S. A., et al.	128	741	10/23/1992
	US-5,312,417	05/17/1994	Wilk, Peter	606	114	07/29/1992
	US-5,313,956	05/24/1994	Knutsson, E. , et al.	128	741	08/04/1992
	US-5,327,902	07/12/1994	Lemmen, R. D.	128	734	05/14/1993
	US-5,333,618	08/02/1994	Lekhtman, G. , et al.	128	734	06/30/1993
	US-5,375,067	12/20/1994	Berchin, G. J.	364	487	12/11/1992
	US-5,383,876	01/24/1995	Nardella, Paul	606	49	03/22/1994
	US-5,474,558	12/12/1995	Neubardt, S. L.	606	79	07/18/1994
	US-5,482,038	01/09/1996	Ruff, L. H.	128	642	06/28/1994
	US-5,540,235	07/30/1996	Wilson, J. R.	128	741	06/30/1994
	US-5,549,656	08/27/1996	Reiss, H. W.	607	48	05/15/1995
	US-5,560,372	10/01/1996	Cory, P. C.	128	741	02/02/1994
	US-5,566,678	10/22/1996	Cadwell, J. A.	128	731	01/05/1995
	US-5,579,781	12/03/1996	Cooke, Thomas H.	128	733	10/13/1994
	US-5,593,429	01/14/1997	Ruff, L. H.	607	116	06/28/1994
	US-5,630,813	05/20/1997	Kieturakis, M. J.	606	46	12/08/1994
	US-5,671,752	09/30/1997	Sinderby, Christer , et al.	128	733	03/31/1995
	US-5,707,359	01/13/1998	Bufalini, Bruno	604	104	11/14/1995
	US-5,711,307	01/27/1998	Smits, Matthijs P.	128	733	04/13/1995
	US-5,775,331	07/07/1998	Raymond, S. A., et al.	128	741	06/07/1995
	US-5,779,642	04/14/1998	Nightengale, Christopher	600	461	02/18/1997
	US-5,797,854	08/25/1998	Hedgecock, J. L.	600	554	08/01/1995
	US-5,814,073	09/29/1998	Bonutti, Peter	606	232	12/13/1996
	US-5,830,151	11/03/1998	Hadzic, A. , et al.	600	554	11/26/1997
	US-5,851,191	12/22/1998	Gozani, S. N.	600	554	07/01/1997
	US-5,853,373	12/29/1998	Griffith, R. L., et al.	600	554	08/05/1996
	US-5,885,219	03/23/1999	Nightengale, C.	600	461	10/21/1997
	US-5,888,196	03/30/1999	Bonutti, Peter M.	600	204	06/05/1995
	US-5,928,158	07/01/1999	Aristides, A.	600	547	03/25/1997

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

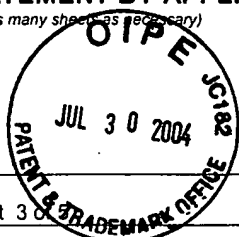
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Sheet 3 of 3

Complete if Known

Application Number	10/608,362
Filing Date	June 26, 2003
First Named Inventor	Miles, Patrick
Group Art Unit	2831
Examiner Name	Unknown

Attorney Docket No: 80100.023US1

	US-5,976,094	11/02/1999	Gozani, S. N., et al.	600	483	02/12/1998
	US-6,004,262	12/21/1999	Putz, D. A., et al.	600	114	05/04/1998
	US-6,027,456	02/22/2000	Feler, C. A., et al.	600	554	07/10/1998
	US-6,038,477	03/14/2000	Kayyali, H. A.	607	72	12/23/1998
	US-6,050,992	04/18/2000	Nichols, C.	606	41	05/19/1997
	US-6,104,957	08/15/2000	Alo, K. M., et al.	607	46	08/21/1998
	US-6,132,386	10/17/2000	Gozani, S. N., et al.	600	554	03/16/1999
	US-6,132,387	10/17/2000	Gozani, S. N., et al.	600	554	03/16/1999
	US-6,135,965	10/24/2000	Tumer, K., et al.	600	476	12/02/1996
	US-6,146,335	11/14/2000	Gozani, S. N.	600	554	03/16/1999
	US-6,161,047	12/12/2000	King, G. W., et al.	607	62	04/30/1998
	US-6,224,549	05/01/2001	Drongelen, W. V.	600	300	04/20/1999
	US-6,259,945	07/10/2001	Epstein, R., et al.	600	547	04/30/1999
	US-6,266,558	07/24/2001	Gozani, Shai N., et al.	600	547	12/01/1998
	US-6,292,701	09/01/2001	Prass, R. L., et al.	607	116	07/29/1999
	US-6,312,392	11/01/2001	Herzon, G. D.	600	554	04/06/2000
	US-6,466,817	10/01/2002	Kaula, N. F., et al.	600	546	06/08/2000
	US-6,500,128	12/31/2002	Marino, J. F.	600	554	06/08/2001
	US-6,564,078	05/13/2003	Marino, J. F., et al.	600	373	06/04/1999
	US-R,E34,390	09/28/1993	Culver, N. D.	128	731	02/28/1991

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
	WO-0066217A1	11/09/2000	Epstein, R., et al.	A61N	1/36	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

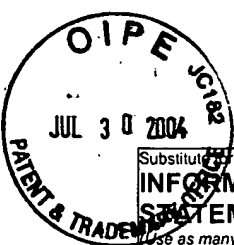
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"Electromyography System", International Search Report, International Application No. PCT/US00/32329, (April 27, 2001), 9 pages	
		"Nerve Proximity and Status Detection System and Method", International Search Report, International Application No. PCT/US01/18606, (October 18, 2001), 6 pages	
		"Relative Nerve Movement and Status Detection System and Method", International Search Report, International Application No. PCT/US01/18579, (January 15, 2002), 6 pages	
		"System and Method for Determining Nerve Proximity, Direction, and Pathology During Surgery", International Search Report, International Application No. PCT/US02/22247, (March 27, 2003), 4 pages	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached



Substitute form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/608,362
Filing Date	June 26, 2003
First Named Inventor	Miles, Patrick
Group Art Unit	2831
Examiner Name	Unknown

Sheet 4 of 5

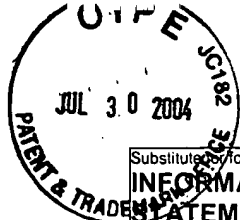
Attorney Docket No: 80100.023US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"System and Methods for Determining Nerve Direction to a Surgical Instrument", <u>International Search Report</u> , International Application No. PCT/US03/02056,(August 12, 2003), 5 pages	
		"Systems and Methods for Performing Percutaneous Pedicle Integrity Assessments", <u>International Search Report</u> , International Application No. PCT/US02/35047,(August 11, 2003), 5 pages	
		"Systems and Methods for Performing Surgery Procedures and Assessments", <u>International Search Report</u> , International Application No. PCT/US02/30617,(June 5, 2003), 4 pages	
		BOSE, et al., "Neurophysiologic Monitoring of Spinal Nerve Root Function During Instrumented Posterior Lumbar Spine Surgery", <u>Spine</u> , 27(13), (2002), pp. 1444-1450	
		CALANCIE, et al., "Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation", <u>Spine</u> , 19(24), (1994), pp. 2780-2786	
		CLEMENTS, et al., "Evoked and Spontaneous Electromyography to Evaluate Lumbosacral Pedicle Screw Placement", <u>Spine</u> , 21(5), (1996),pp. 600-604	
		FORD, et al., "Electrical Characteristics of Peripheral Nerve Stimulators Implications for Nerve Localization", <u>Regional Anesthesia</u> , 9, (1984), pp. 73-77	
		GLASSMAN, et al., "A Prospective Analysis of Intraoperative Electromyographic Monitoring of Pedicle Screw Placement With Computed Tomographic Scan Confirmation", <u>Spine</u> , 20(12), (1995), pp. 1375-1379	
		GREENBLATT, et al., "Needle Nerve Stimulator-Locator: Nerve Blocks with a New Instrument for Locating Nerves", <u>Anesthesia & Analgesia</u> , 41(5), (1962), pp. 599-602	
		HOLLAND, N. , "Intraoperative Electromyography During Thoracolumbar Spinal Surgery", <u>Spine</u> , 23(17), (1998), pp. 1915-1922	
		LENKE, et al., "Triggered Electromyographic Threshold for Accuracy of Pedicle Screw Placement", <u>Spine</u> , 20 (14), (1995),1585-1591	
		MAGUIRE, et al., "Evaluation of Intrapedicular Screw Position Using Intraoperative Evoked Electromyography", <u>Spine</u> , 20(9), (1995), pp. 1068-1074	
		MARTIN, et al., "Initiation of Erection and Semen Release by Rectal Probe Electrostimulation (RPE)", <u>The Williams & Wilkins Co.</u> , (1983), pp. 637-642	
		PITHER, et al., ""The Use of Peripheral Nerve Stimulators for Regional Anesthesia: Review of Experimental Characteristics, Technique, and Clinical Applications"", <u>Regional Anesthesia</u> , (1985), pp. 10:47-53	
		RAJ, et al., "Infraclavicular Brachial Plexus Block - A New Approach", <u>Anesthesia and Analgesia</u> , (52)6, (1973), pp. 897-904	
		RAJ, et al., "The Use of Peripheral Nerve Stimulators For Regional Anesthesia", <u>Clinical Issues In Regional Anesthesia</u> , 1 (4), (1985), pp. 1-6	
		RAJ, et al., "Use of The nerve Stimulator of Peripheral Blocks", <u>Regional Anesthesia</u> , (apr-jun 1980), pp. 14-21	

EXAMINER

DATE CONSIDERED



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/608,362
Filing Date	June 26, 2003
First Named Inventor	Miles, Patrick
Group Art Unit	2831
Examiner Name	Unknown

Sheet 5 of 5

Attorney Docket No: 80100.023US1

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		RAYMOND, et al., "The Nerve Seeker: A System for Automated Nerve Localization", <u>Regional Anesthesia</u> , 17(3), (1992), pp. 151-162	
		SHAFIK, "Cavernous Nerve Simulation through an Extrapelvic Subpubic Approach: Role in Pencil Erection", <u>Eur. Urol.</u> , 26, (1994), pp. 98-102	
		TOLEIKIS, et al., "The Usefulness of Electrical Stimulation for Assessing Pedicle Screw Replacements", <u>Journal of Spinal Disorder</u> , 13(4), (2000), pp. 283-289	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached